Reviewer’s report

Title: Intervention to reduce excessive improve alcohol consumption & improve co-morbid outcomes in hypertensive or depressed primary care patients: two parallel randomised feasibility trials

Version: 1 Date: 23 January 2014

Reviewer: Natasha Cohen

Reviewer’s report:

Major Compulsory Revisions

1. “No date limit was set on the searches apart from those conducted at the last five practices recruited, where, based on experiences with earlier practices, the depression codes were limited to the preceding year” – this sentence seems to be written quite vaguely. I am not sure what the patients cannot be tracked based on the corresponding codes from the previous year. As well, a pilot study could have helped to uncover some of these underlying issues, rather than having what seems like a major protocol deviation, and may cause inequalities between clusters introducing a source of bias.

2. Please specify the sensitivity and specificity of the AUDIT tool for detecting alcoholism and which specific population it has previously been validated in (other than primary care setting). Same for the PHQ-9.

3. Switch the order of Intervention and Measures sections.

4. No pre-existing hypothesis for successful outcomes, including no parameters for the feasibility of conducting the full study to ensure adequate power to detect a clinically relevant decrease in alcohol use (i.e. based on recruitment in your pilot, for how long and how many centres would have to be enrolled to power your study adequately, this requires a sample size calculation based on your study data).

5. Regarding randomization, it is unclear if allocation was in fact random, no mention of allocation concealment, which would be hard to do in a counselling intervention, but still possible given that both groups got pamphlets.

6. Include details about measures taken to improve response rates, including repeated contact by mail, phone call, reinforcement by GP, if any, and rationale for them or their absence.

7. The analysis section has no information regarding the statistical methods used to obtain the results presented in the Characteristics at baseline section. As well, what type of approach is planned for the trial, intention to treat or per protocol. The reason this is important is because in the description of the pilot trials in both the hypertension and depression arm, the patients who were lost to follow up should be included in your analysis with previously determined statistical approaches for missing data (eg: data carried forward, vs assume return to
baseline, and perform sensitivity analysis to verify the primary outcome results).

8. Please include a sample size calculation for the number clusters required to answer your desired question based on your estimate of efficacy, and measure the feasibility of performing this study based on your own recruitment and drop-out rates.

9. No outcomes section. This is essential. It was partly described in the Measures section, but there needs to be more detail about what the primary and secondary outcomes are, what is considered significant for the feasibility parameters.

10. No flow diagram included. For guidelines on how this should look for a cluster RCT refer to: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC381234/figure/fig1/

11. Typo in title: Intervention to reduce excessive (remove: improve) alcohol consumption & improve co-morbid outcomes in hypertensive or depressed primary care patients: two parallel (add: cluster) randomised feasibility trials.

Minor Essential Revisions

1. It is unclear how the screening for patients occurs exactly, namely who is performing the screening, if there are any guidelines on who is allowed to do screening, how these people are trained to adhere to the protocol, and if there are any second reviewers for inclusion of included eligible patients.

2. More detail is required for the diagnostic criteria for hypertension. What blood pressure values are considered hypertension. What is the rationale for not repeating measurements during the clinical assessment, as recommended by the NICE guidelines to confirm the diagnosis. This should be addressed in the Methods section (in addition to the mention in the discussion).

3. “A further practice withdrew from the study without indicating whether their prevalence data could be included.” State whether there were any attempts made to contact this practice to find out why they dropped out.

4. Regarding the intervention more details regarding the details of how participant were assessed in the GP clinics, or were they brought to the investigator’s offices. Was it coordinated with the patients directly or with the participating practices.

5. Sample size was determined based on recommendations as a rule of thumb. However, these do not apply to cluster randomized studies. Not to say the sample size was not valid, but the justification for this is inaccurate.

6. Altogether, there needs to be improvement of the implementation process such that this trial can truly be reproduced on a larger scale.

7. No specific dates for recruitment (beginning, end) and follow up.

8. It is recommended to estimate the effect size, despite the imprecision of an estimate based on a pilot, but since it is the best available evidence at this time to calculate a sample, it should be done. Be mindful of the fact that this is a cluster randomized trial, and therefore the estimate should be for the number of clusters needed to power the minimal clinically important difference of your
primary outcome.

Discretionary Revisions
1. Please define the term “surgery” as it may be misconstrued as meaning an operation or change it to another term/synonym.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests